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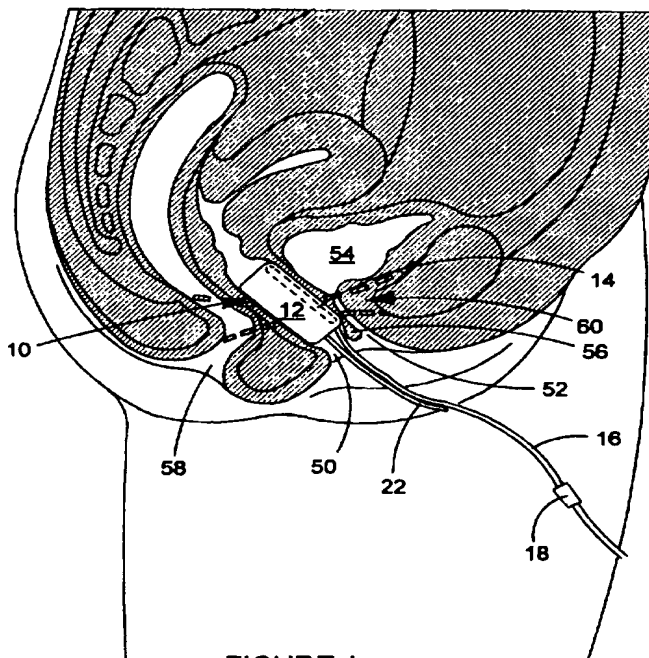
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WO 96/01084 A **FR 002228464 A** **US 5609559 A**
US 5299581 A **US 5041077 A**

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(54) Abstract Title
Inflatable pessary

(57) An inflatable pessary (10) adapted to be placed in a female vagina comprising elongate support means (12), inflatable restriction means (14) being connected to the support means, and an inflation valve (18) located remote from said inflatable restriction means, wherein the restriction means is arranged such that when inflated, pressure is applied outwardly to the walls of the vagina. The pessary may also include a second inflatable restriction means where the restriction means may be independently deflated and inflated. The pessary may be used to provide artificial continence, to conduct perineometry or to provide sexual stimulation.

**FIGURE 1**

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy. The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995. This print takes account of replacement documents submitted after the date of filing to enable the application to comply with the formal requirements of the Patents Rules 1995

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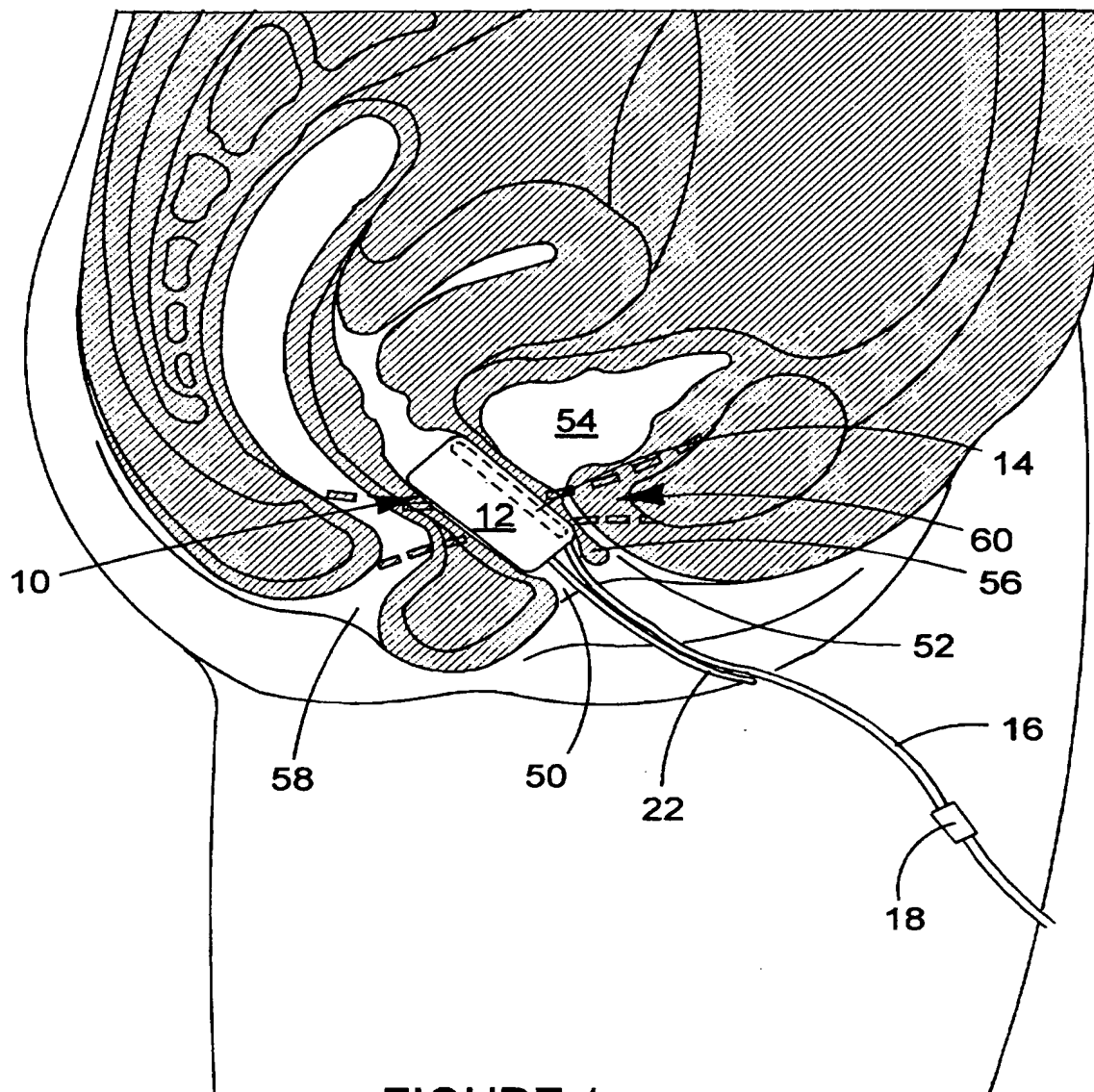


FIGURE 1

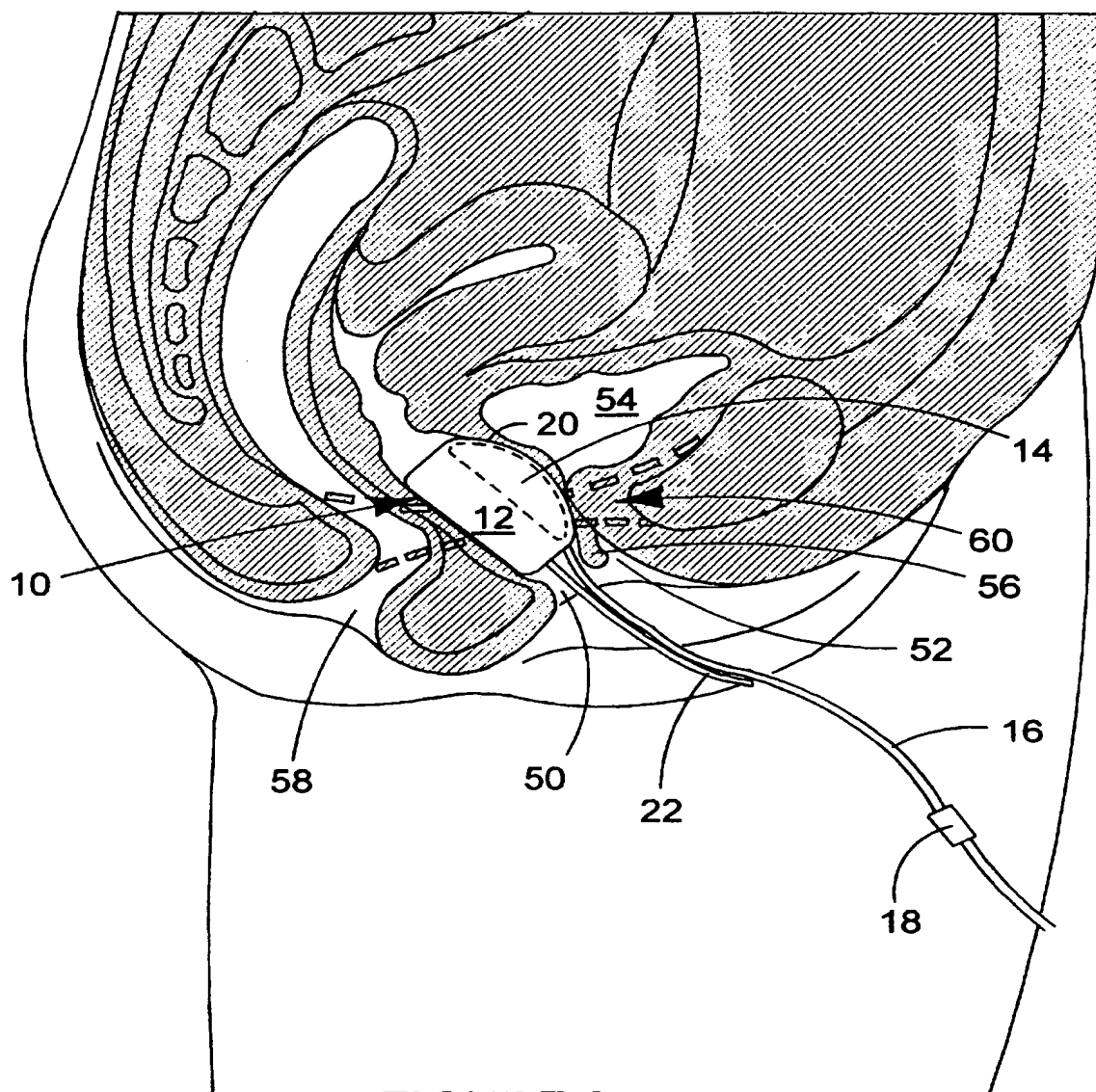


FIGURE 2

INFLATABLE PESSARY

This invention relates to an inflatable pessary and more particularly to a device which is adapted to be placed in the female vagina to prevent or reduce the effects of incontinence. Such a device, in one embodiment, is used to produce artificial patient continence. In another embodiment, the pessary is adapted to provide stimulation to the G-spot. In a further embodiment, the pessary is adapted for use in perineometry.

One aspect of the present invention provides an inflatable pessary adapted to be placed in a female vagina comprising elongate support means, inflatable restriction means being connected to the support means, and an inflation valve located remote from said inflatable restriction means, wherein the restriction means is arranged such that when inflated, pressure is applied outwardly to the walls of the vagina.

According to an optional feature of this aspect of the invention, the inflatable pessary may be adapted for use as an artificial sphincter. Alternatively, the pessary may be adapted for use in perineometry. Alternatively, the pessary may be adapted for providing sexual stimulation.

Embodiments of the invention will now be described by way of example, with reference to the accompanying drawings, in which:

FIGURE 1 is a sectional view of the inflatable pessary which is used to produce continence according to one embodiment of the present invention with the inflatable restriction means uninflated; and

FIGURE 2 is a sectional view of the inflatable pessary which is used to produce continence of the embodiment illustrated in Figure 1 with the inflatable restriction means inflated

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Referring first to Figure 1, there is shown a cross section of an inflatable pessary 10. The pessary 10 comprises a support 12 made from rubber or other suitable material.

Preferably, the support 12 is substantially cylindrical in shape and made from medical grade silicone rubber. The support 12 may be rounded at its ends to aid insertion and removal. An inflatable chamber 14 is provided on the outer surface of the cylindrical support 12 and is also made from rubber or other suitable material. The chamber 14 may be formed integrally with the support 12, or be secured thereon by a heat welding process, for example.

A tube 16 again made from rubber or other suitable material extends from the inflatable chamber 14 and is welded about an aperture (not shown) provided in the inflation chamber 14. In use, the free end of the tube extends out of the vaginal opening so that the pessary 10 can be attached to a source of pressure fluid and the chamber 14 inflated. This tube allows the chamber 14 to be inflated or deflated when required. A suitable control valve 18 is preferably provided at an accessible position on the tube to maintain the pressure in the chamber 14 when the source of pressure fluid is removed. Preferably, the control valve should be compact and easy to operate whilst being capable of maintaining the inflation of the chamber 14 for long periods of time.

In the embodiment outlined above, the source of pressure fluid is a hand pump or a standard syringe, which due to space limitations, are preferably detachable. The pump/syringe pumps air, or in alternative embodiments, a liquid such as water through an air/watertight socket (not shown). This may be a simple push-fit, or a known type of fitting.

In this embodiment a cord 20 of suitable material is provided to aid the removal of the pessary from the vagina, when desired. However, in alternative classes of embodiment, the tube 16 may perform this function.

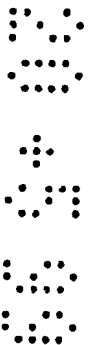
The invention according to the embodiment illustrated in Figures 1 and 2 can be used to assist patient continence by placing the pessary 10 in the vagina 50 with the chamber 14 uninflated and orientated substantially upwardly and forwardly so the

outer surface 20 of the chamber 14 is in contact with the wall 56 separating the vagina 50 from the urethra 52. The chamber 14 is then inflated to a sufficient pressure whereby the outer surface 20 is pressed firmly against the wall 56.

- 5 The effect of the inflated bladder 18 is to substantially close off the urethra 52 and thereby to prevent or minimise fluid flow therethrough. One advantage of this device is that pressure on the urethra can be varied by altering the pressure within chamber 14. When the user wishes to urinate, the control valve 18 is opened to allow the chamber 14 to deflate, thereby reopening the urethra, allowing urine to pass
10 therethrough. Once urination is complete, the chamber 14 is reinflated using the detachable pump/syringe to close off the urethra.

- In alternative embodiments (not shown), the device may be used for substantially preventing incontinence through the anus 58 by rotating the device through 180 ° and
15 inflating it in a similar manner to substantially close off the anus. Alternatively, the pessary may be provided with two chambers spaced substantially 180 ° apart on the support, and selectively inflatable by using two separate tubes, or one tube with valve means to switch between inflating either one chamber or the other, thereby allowing
20 either or both of the urethra and anus to be closed off.

- In a further alternative embodiment (not shown), the pessary may be used for conducting perineometry. In this embodiment, two chambers spaced substantially 180° apart are provided on the support of the pessary. The pessary is inserted rotated through 90° to the views shown in Figures 1 and 2, and thereby contacts the side
25 walls, rather than front and rear walls of the vagina 50. The inflation of the chambers allows the performance of the pelvic floor 60 to be assessed when used in conjunction with electronic measuring equipment which may be provided separately, or built in to the support.



In a further alternative embodiment (not shown), the pessary, when inflated may be used in conjunction with oscillating/vibrating means to stimulate the G-spot of the user, thereby causing sexual arousal.

- 5 It will be appreciated that a device of the invention has the advantage of providing a light relatively unobtrusive solution to the problems associated with incontinence, as well as in variant form assessing the performance of the pelvic floor or providing sexual stimulation. It will be appreciated that the shape of the inflatable chamber(s) and the support, can be varied according to particular circumstances , for example,
- 10 when a chamber is intended to close off the anus.



CLAIMS

1. An inflatable pessary adapted to be placed in a female vagina comprising elongate support means, inflatable restriction means being connected to the support means, and an inflation valve located remote from said inflatable restriction means, wherein the restriction means is arranged such that when inflated, pressure is applied outwardly to the walls of the vagina.
2. A pessary according to claim 1 wherein the inflatable restriction means comprises a chamber located on the elongate surface of the support means.
3. A pessary according to claim 1 or claim 2 wherein a tube extends from the inflatable restriction means to the inflation valve.
4. A pessary according to claim 3 wherein inflation means may be releasably secured to the tube so as to effect inflation and/or deflation of the inflatable restriction means.
5. A pessary according to any preceding claim wherein removal means is further provided to assist in the removal of the pessary from the vagina.
6. A pessary according to claim 5 wherein the removal means comprises a cord secured to an end surface of the support means that may be engaged by the user to effect removal.
7. A pessary according to claim 5 wherein the removal means comprises the tube that may be engaged by the user to effect removal.
8. A pessary according to any preceding claim wherein the support means is substantially cylindrical in shape.

9. A pessary according to any preceding claim wherein measuring means is provided in association with the pessary so as to monitor the performance of the pelvic floor.

5 10. A pessary according to claim 9 wherein the measuring means is built into the support.

11. A pessary according to claim 9 wherein the measuring means is built into the control valve.

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12. A pessary according to any preceding claim wherein a second inflatable restriction means is located substantially 180° apart from the first inflatable restriction means.

15 13. A pessary according to claim 12 wherein the first and second inflatable restriction means may be independently inflated and deflated.

14. A pessary according to any preceding claim adapted to provide artificial patient continence.

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15. A pessary according to any preceding claim adapted to provide sexual stimulation.

25 16. A pessary adapted to be placed in the female vagina comprising an elongate body portion to which an inflatable chamber is secured, the chamber being attached to an inflation control valve by a tube, wherein the pessary is so constructed and arranged such that the inflation of the chamber by a pump or syringe releasably attached to the free end of the tube causes the pressure to be applied outwardly to the walls of the vagina.

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17. A method of providing artificial continence and/or conducting perineometry comprising the steps of:
- i) inserting a pessary according to any preceding claim into the vagina with the inflatable restriction means/chamber correctly orientated.
 - 5 ii) inflating the artificial restriction means using a detachable inflation means.
 - iii) closing the inflation valve.
 - iv) removing the detachable inflation means.
- 10 18. A pessary substantially as hereinbefore described.
19. A pessary substantially as hereinbefore described with reference to Figures 1 and 2 of the drawings.



INVESTOR IN PEOPLE

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Examiner: Susan Chalmers
(Mrs)

Claims searched: 1-19

Date of search: 3 November 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R: REU

Int Cl (Ed.7): A61F: 2/00, 6/08, 6/12

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	WO 96/01084 A (TUTRONE) see eg Figures 1-3 and page 12 lines 12-29	1-5,7,8, 12-17
X	US 5609559 (WEITZER) see parts 12 and 70 in the Figures	1-5,7,14-17
X	US 5299581 (DONNELL ET AL) see parts 36,39,41 in Figures 5-7 and column 6 lines 47-54	1-3,5-8, 14-16
X	US 5041077 (KULICK) see parts 23,63 and 31,71 in the Figures	1-5,7,14-17
X	FR 2228464 (HEGUY) see whole document	1-5,7,14-17

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.

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A Document indicating technological background and/or state of the art.
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